



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0247]

Agency Information Collection Activities; Proposed Collection; Submission for Office of Management and Budget Review; Guidance for Industry on Formal Meetings With Sponsors and Applicants for Prescription Drug User Fee Act Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment

does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on

<http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2012-N-0247 for "Agency Information Collection Activities; Proposed Collection; Submission for Office of Management and Budget Review; Guidance for Industry on Formal Meetings With Sponsors and Applicants for PDUFA Products."

Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION”. The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the

prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0429.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry on Formal Meetings With Sponsors and Applicants for PDUFA Products

OMB Control Number 0910-0429--Extension

This information collection approval request is for FDA guidance on the procedures for formal meetings between FDA and sponsors or applicants regarding the development and review of PDUFA products. The guidance describes procedures for requesting, scheduling, conducting, and documenting such formal meetings. The guidance provides information on how the Agency will interpret and apply section 119(a) of the Food and Drug Administration Modernization Act (FDAMA) (Pub. L. 105-115), specific PDUFA goals for the management of meetings associated with the review of human drug applications for PDUFA products, and provisions of existing regulations describing certain meetings (§§ 312.47 and 312.82 (21 CFR 312.47 and 312.82)).

The guidance describes two collections of information: The submission of a meeting request containing certain information and the submission of an information package in advance

of the formal meeting. Agency regulations at §§ 312.47(b)(1)(ii), (1)(iv), and (2) describe information that should be submitted in support of a request for an end-of-phase 2 meeting and a pre-NDA meeting. The information collection provisions of § 312.47 have been approved by OMB control number 0910-0014. However, the guidance provides additional recommendations for submitting information to FDA in support of a meeting request. As a result, FDA is submitting additional estimates for OMB approval.

I. Request for a Meeting

Under the guidance, a sponsor or applicant interested in meeting with the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER) should submit a meeting request to the appropriate FDA component as an amendment to the underlying application. FDA regulations (§§ 312.23, 314.50, and 601.2 (21 CFR 312.23, 314.50, and 601.2)) state that information provided to the Agency as part of an investigational new drug application (IND), new drug application (NDA), or biological license application (BLA) must be submitted with an appropriate cover form. Form FDA 1571 must accompany submissions under INDs and Form FDA 356h must accompany submissions under NDAs and BLAs. Both forms have valid OMB control numbers as follows: Form FDA 1571--OMB control number 0910-0014 and Form FDA 356h--OMB control number 0910-0338.

In the guidance document, CDER and CBER ask that a request for a formal meeting be submitted as an amendment to the application for the underlying product under the requirements of §§ 312.23, 314.50, and 601.2; therefore, requests should be submitted to the Agency with the appropriate form attached, either Form FDA 1571 or Form FDA 356h. The Agency recommends that a request be submitted in this manner for two reasons: (1) To ensure that each request is kept in the administrative file with the entire underlying application, and (2) to ensure

that pertinent information about the request is entered into the appropriate tracking databases.

Use of the information in the Agency's tracking databases enables the Agency to monitor progress on the activities attendant to scheduling and holding a formal meeting and to ensure that appropriate steps will be taken in a timely manner.

Under the guidance, the Agency requests that sponsors and applicants include in meeting requests certain information about the proposed meeting. Such information includes:

- Information identifying and describing the product;
- the type of meeting being requested;
- a brief statement of the purpose of the meeting;
- a list of objectives and expected outcomes from the meeting;
- a preliminary proposed agenda;
- a draft list of questions to be raised at the meeting;
- a list of individuals who will represent the sponsor or applicant at the meeting;
- a list of Agency staff requested to be in attendance;
- the approximate date that the information package will be sent to the Agency; and
- suggested dates and times for the meeting.

This information will be used by the Agency to determine the utility of the meeting, to identify Agency staff necessary to discuss proposed agenda items, and to schedule the meeting.

II. Information Package

A sponsor or applicant submitting an information package to the Agency in advance of a formal meeting should provide summary information relevant to the product and supplementary information pertaining to any issue raised by the sponsor, applicant, or Agency. The Agency recommends that information packages generally include:

- Identifying information about the underlying product;
- a brief statement of the purpose of the meeting;
- a list of objectives and expected outcomes of the meeting;
- a proposed agenda for the meeting;
- a list of specific questions to be addressed at the meeting;
- a summary of clinical data that will be discussed (as appropriate);
- a summary of preclinical data that will be discussed (as appropriate); and
- chemistry, manufacturing, and controls information that may be discussed (as appropriate).

The purpose of the information package is to provide Agency staff the opportunity to adequately prepare for the meeting, including the review of relevant data concerning the product. Although FDA reviews similar information in the meeting request, the information package should provide updated data that reflect the most current and accurate information available to the sponsor or applicant. The Agency finds that reviewing such information is critical to achieving a productive meeting.

The collection of information described in the guidance reflects the current and past practice of sponsors and applicants to submit meeting requests as amendments to INDs, NDAs, and BLAs and to submit background information prior to a scheduled meeting. Agency regulations currently permit such requests and recommend the submission of an information package before an end-of-phase 2 meeting (§§ 312.47(b)(1)(ii) and (iv)) and a pre-NDA meeting (§ 312.47(b)(2)).

Description of Respondents: A sponsor or applicant for a drug or biological product who requests a formal meeting with the Agency regarding the development and review of a PDUFA

product.

Burden Estimate: Provided in this document is an estimate of the annual reporting burden for the submission of meeting requests and information packages under the guidance.

III. Request for a Formal Meeting

Based on data collected from the review divisions and offices within CDER and CBER, FDA estimates that approximately 1,099 sponsors and applicants (respondents) request approximately 2,366 formal meetings with CDER annually and approximately 175 respondents request approximately 264 formal meetings with CBER annually regarding the development and review of a PDUFA product. The hours per response, which is the estimated number of hours that a respondent would spend preparing the information to be submitted with a meeting request in accordance with the guidance, is estimated to be approximately 10 hours. Based on FDA's experience, the Agency expects it will take respondents this amount of time to gather and copy brief statements about the product and a description of the purpose and details of the meeting.

IV. Information Package

Based on data collected from the review divisions and offices within CDER and CBER, FDA estimates that approximately 959 respondents submitted approximately 1,901 information packages to CDER annually and approximately 142 respondents submitted approximately 193 information packages to CBER annually prior to a formal meeting regarding the development and review of a PDUFA product. The hours per response, which is the estimated number of hours that a respondent would spend preparing the information package in accordance with the guidance, is estimated to be approximately 18 hours. Based on FDA's experience, the Agency expects it will take respondents this amount of time to gather and copy brief statements about the product, a description of the details for the anticipated meeting, and data and information that

generally would already have been compiled for submission to the Agency.

In the Federal Register of May 20, 2015 (80 FR 29010), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

As stated earlier, the guidance provides information on how the Agency will interpret and apply section 119(a) of FDAMA, specific PDUFA goals for the management of meetings associated with the review of human drug applications for PDUFA products, and provisions of existing regulations describing certain meetings (§§ 312.47 and 312.82). The information collection provisions in § 312.47 concerning end-of-phase 2 meetings and pre-NDA meetings have been approved by OMB control number 0910-0014. However, the guidance provides additional recommendations for submitting information to FDA in support of a meeting request. As a result, FDA is submitting for OMB approval these additional estimates.

Table 1.--Estimated Annual Reporting Burden¹

| Meeting Requests and Information Packages | No. of Respondents | No. of Responses Per Respondent | Total Annual Responses | Average Burden per Response | Total Hours |
|---|--------------------|---------------------------------|------------------------|-----------------------------|-------------|
| Meeting Requests | | | | | |
| CDER | 1,099 | 2.15 | 2,366 | 10 | 23,660 |
| CBER | 175 | 1.51 | 264 | 10 | 2,640 |
| Total | | | | | 26,300 |
| Information Packages | | | | | |
| CDER | 959 | 1.99 | 1,901 | 18 | 34,218 |
| CBER | 142 | 1.36 | 193 | 18 | 3,474 |
| Total | | | | | 37,692 |
| Grand Total | | | | | 63,992 |

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: October 2, 2015.

Leslie Kux,

Associate Commissioner for Policy.